

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/030,137	STOTT, KELVIN	
	<b>Examiner</b>	<b>Art Unit</b>	
	Samuel W. Liu	1653	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 9/12/05.
2. ☒ The allowed claim(s) is/are 1-28,43,46 and 47.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☒ All    b) ☐ Some\*    c) ☐ None    of the:
  1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☒ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
  - (b) ☒ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |  |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)  | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)                                  |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date <u>11/23/05</u> . |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment  |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material          | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance                         |
|   | 9. <input type="checkbox"/> Other _____.   |

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### DETAILED ACTION

This Office action is in response to the applicants' amendment filed 9/12/05, which amends claims 1-3, adds claims 46 and 47, and cancels claims 29-42 and 44-45 has been entered. Applicants' request (filed 8/5/05) for extension of time of twom months also has been entered. The following Offcie action is applied to the pending claims 1-28, 43 and 46-47.

### EXAMINER'S AMENDMENT

An Examiner's Amendment to the record appears below. Should the change and/or additions be unacceptable to Applicant, an amendment may be filed as provided by 37 C.F.R. § 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no latter than payment of the Issue Fee.

Authorization for this Examiner's Amendment was given in a telephone interview with John C. Holman on 11/23/2005. Applicants agree to the examiner proposed amendment to claims 1-28, 43 and 46-47 (see below).

#### Amendments to the claim:

The pending claims 1-28, 43 and 46-47 have been amended as follows. Please replace the previous claims with the claims shown below.

Claim 1 (*Amended*): Change "A chemical compound or composition comprising peptide, wherein" to "**A peptide comprising**"; and in claim item c), lines 7-8, change "lie along either the first edge or the second edge" to "lie along the first edge **and** the second edge".

Claim 2 (*Amended*): Change "The chemical compound or composition" to "**The peptide**".

Claim 3 (*Amended* Change "The chemical compound or composition" to "**The peptide**".

Claim 4 (*Amended*): Change "The chemical compound or composition" to "**The peptide**".

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Claim 5 (*Amended*): Change “The chemical compound or composition” to “**The peptide**”.

Claim 6 (*Amended*): Change “The chemical compound or composition” to “**The peptide**”.

Claim 7 (*Amended*): Change “The chemical compound or composition” to “**The peptide**”.

Claim 8 (*Amended*): Change “The chemical compound or composition” to “**The peptide**”.

Claim 9 (*Amended*): Change “The chemical compound or composition” to “**The peptide**”.

Claim 10 (*Amended*): Change “The chemical compound or composition” to “**The peptide**”.

Claim 11 (*Amended*): Change “The chemical compound or composition” to “**The peptide**”.

Claim 12 (*Amended*): Change “The chemical compound or composition” to “**The peptide**”.

Claim 13 (*Amended*): Change “The chemical compound or composition” to “**The peptide**”.

Claim 14 (*Amended*): Change “The chemical compound or composition” to “**The peptide**”.

Claim 15 (*Amended*): Change “The chemical compound or composition” to “**The peptide**”; and change “and *tert*-leucine or  $\beta$ -hydroxyvaline” to “*tert*-leucine and  $\beta$ -hydroxyvaline”.

Claim 16 (*Amended*): ~~The chemical compound or composition~~ peptide according to claim 1 wherein the target  $\beta$ -strand is formed by the Alzheimer's A $\beta$  peptide, and the

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$\beta$ -strand-forming section of peptide binds specifically as a  $\beta$ -strand to part or all of the KLVFFAE sequence (SEQ ID NO:3) within the target  $\beta$ -strand in the parallel orientation, thereby forming a parallel  $\beta$ -sheet complex wherein consecutive residues of the  $\beta$ -strand-forming section of peptide lie directly opposite consecutive residues of the ~~KLVFFAE sequence~~ SEQ ID NO:3 in the same order.

Claim 17 (*Amended*): The ~~chemical compound or composition~~ peptide according to claim 1 wherein the target  $\beta$ -strand is formed by the Alzheimer's A $\beta$  peptide, and the  $\beta$ -strand-forming section of peptide binds specifically as a  $\beta$ -strand to part or all of the KLVFFAE sequence (SEQ ID NO:3) within the target  $\beta$ -strand in the antiparallel orientation, thereby forming an antiparallel  $\beta$ -sheet complex wherein consecutive residues of the  $\beta$ -strand-forming section of peptide lie directly opposite consecutive residues of the ~~KLVFFAE sequence~~ SEQ ID NO:3 in reverse order.

Claim 18 (*Amended*): Change "The chemical compound or composition" to "**The peptide**".

Claim 19 (*Amended*): Change "The chemical compound or composition" to "**The peptide**".

Claim 20 (*Amended*): Change "The chemical compound or composition" to "**The peptide**".

Claim 21 (*Amended*): Change "The chemical compound or composition" to "**The peptide**".

Claim 22 (*Amended*): Change "The chemical compound or composition" to "**The peptide**".

Claim 23 (*Amended*): Change "The chemical compound or composition" to "**The peptide**".

Claim 24 (*Amended*): The ~~chemical compound or composition~~ peptide according to claim 23, wherein the functional component is selected from the group consisting of:  
a component which strengthens the binding of the  $\beta$ -strand-forming section of peptide to the target  $\beta$ -strand;  
a component which enhances specificity of association of the  $\beta$ -

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strand-forming section of peptide to the target  $\beta$ -strand;

a component which enables the  $\beta$ -strand-forming section of peptide to cross cell membranes, the blood-brain barrier or any other biological barrier;

a component which causes the ~~compound/composition~~ peptide to target specific organs, cells, or molecules;

a component which allows the ~~compound/composition~~ peptide to be traced or detected;

an atom or group that contains a radioactive or magnetically active nucleus;

a fluorescent, colored, or other spectroscopically detectable group;

a group which contains an unpaired electron and thereby acts as a spin label;

a group which contains the 2,2,5,5-tetramethyl-1-pyrrolidinyloxy (PROXYL) group or the 2,2,6,6-tetramethyl-1-piperidinyloxy (TEMPO) group;

a solid matrix, resin, or support;

an enzyme, hormone, antibody, transcription factor, or other protein molecule;

a group that binds specifically to a particular protein; and a cytotoxic molecule.

Claim 25 (*Amended*): Change “The chemical compound or composition” to “**The peptide**”.

Claim 26 (*Amended*): Change “The chemical compound or composition” to “**The peptide**”.

Claim 27 (*Amended*): Change “The chemical compound or composition” to “**The peptide**”.

Claim 28 (*Amended*): Change “The chemical compound or composition” to “**The peptide**”.

Claim 43 (*Amended*): A pharmaceutical ~~compound or composition~~ comprising the peptide according to claim 1.

Claim 46 (*Amended*): Change “The chemical compound or composition” to “**The peptide**”.

Claim 47 (*Amended*): Change “A chemical compound or composition comprising a peptide, wherein” to “**A peptide comprising**”; and in claim item c), lines 7-8, change

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“lie along either the first edge or the second edge” to “lie along the first edge **and** the second edge”.

**Amendment to the specification:**

**Amendments to the specification:**

In abstract is amended as follows (in one paragraph and in a separate sheet):

Peptide is disclosed which is capable of binding to  $\beta$ -strand in a separate peptide-containing molecule to form  $\beta$ -sheet, wherein said peptide is selectively  $N\alpha$ -substituted in one edge (first) of the  $\beta$ -strand-forming section of said peptide while the other edge (second) in the opposite orientation to the first edge in view of peptide backbone plane remains  $N\alpha$ -unsubstituted. Such the  $N\alpha$ -substituted peptide is capable of preventing association of said peptide with other  $\beta$ -strand (target) but permits interaction of said peptide with target  $\beta$ -strand in separate peptide-containing molecules through the  $N\alpha$ -unsubstituted edge.

**Objection to the drawings:**

The drawing filed 9/12/05 is objected to because (i) the SC (side chain) moieties presented in the “peptide ribbon plane” of said drawing is inappropriate in which  $\alpha$ -carbons to which the SC moieties link appear to be missing; and (ii) explanation or legend of the drawing should not be presented in the drawing, e.g., “*SCs extend from either side of the peptide (or ribbon) plane- i.e., into/out of the paper*”; it should belongs to brief description of the drawing thereof. In addition, the drawing thereof does not contain a label indicating Figure number in accordance with Figures 1-6 filed 1/28/02.

The following is an **Examiner's Statement of Reasons for Allowance**:

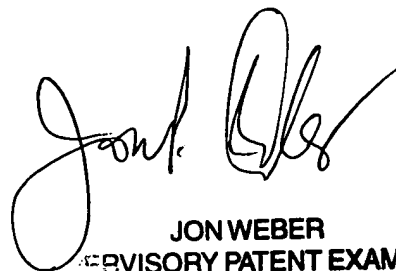
The rejections under 35 USC 102 in the office action mailed 3/1/05 are withdrawn in light of that the applicants' amendment to claims obviates the rejections. The Prior art does not teach a peptide comprising a  $\beta$ -strand forming section which has the two edges define/described in the claims and the drawing filed 9/12/05 wherein one edge comprises at least one  $N\alpha$ -substituent which hinders the interaction of said edge with another  $\beta$ -strand(s) in a separate peptide-containing molecule.

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Therefore, 1-28, 43 and 46-47 are allowed.

A handwritten signature in cursive script, appearing to read 'S.W. Liu'.

Samuel W. Liu, Ph.D.  
Art Unit 1653, Examiner  
November 23, 2005

A handwritten signature in cursive script, appearing to read 'Jon Weber'.

**JON WEBER**  
**SUPERVISORY PATENT EXAMINER**

**Abstract**

Peptide is disclosed which is capable of binding to  $\beta$ -strand in a separate peptide-containing molecule to form  $\beta$ -sheet, wherein said peptide is selectively  $N\alpha$ -substituted in one edge (first) of the  $\beta$ -strand-forming section of said peptide while the other edge (second) in the opposite orientation to the first edge in view of peptide backbone plane remains  $N\alpha$ -unsubstituted. Such the  $N\alpha$ -substituted peptide is capable of preventing association of said peptide with other  $\beta$ -strand (target) but permits interaction of said peptide with target  $\beta$ -strand in separate peptide-containing molecules through the  $N\alpha$ -unsubstituted edge.